



PATENT SPECIFICATION ⁽²¹⁾ 58,504 /69

Class (52) 87.4; 57.41.

Int. Cl. (51) A01 F; B65B.

Application Number (21) 58504/69.
Lodged (22) 24th July, 1969.

Complete Specification
entitled (54) NEEDLE, SUTURE PACKAGE.

Lodged (23) 24th July, 1969.
Accepted (44) Lapsed under Section 47D(1).
Published (41) 28th January, 1971.

Convention Priority (30) 25th April, 1969, United States of America, 819552.

Applicant (71) DEKNATEL INC.

Actual Inventor (72) LEONARD D. KURTZ.

Related Art (56) NIL

24949

The following statement is a full description of this invention, including the best method of performing it known to US :

41-59-2D-15P.C.

F. D. Atkinson, Government Printer, Canberra

BEST AVAILABLE COPY

This invention relates to surgical packages, and in particular it relates to an improved needle suture package and an improved method for packaging needle sutures.

A needle suture is generally employed in the intense environment of an operating room at least under conditions where the person applying the suture, for example a surgeon, must concentrate on the condition of a patient. In this situation, unnecessary handling of the suture, such as for removal of a suture from a package, would divert the attention of the surgeon from his main area of concern. Moreover, in an operating room, even the efforts of attendants such as nurses should not be wasted in performing unnecessary tasks. With this in mind, it has been recognized heretofore that the suture package should be designed in such manner as to facilitate handling of the suture. However, previous suture packages have not been entirely satisfactory in maximizing expeditious handling of the needle suture.

To fully understand the problems encountered in designing a suture package, the environment in which the suture is used must be considered in greater detail. As noted above, the surgeon will normally rely upon other personnel, for example a nurse, to remove the suture from the package and hand it to him

for use at 1
ally, the n
age and lay
towel so thr
Then, when 1
will reach 1
suture towel
can be seen
nurse's time
suture. This
when it is 1
nurse in an
expeditious

Acc
age was prov
reduced to a
was provided
separate con
by virtue of
of removing
ing it on th
Rather, when
suture, she
suture still
tained becau

use at the precise moment when needed. Generally, the nurse must remove the suture from the package and lay it out uncoiled and straight on a suture towel so that it can be reached quickly when needed. Then, when the surgeon calls for the suture the nurse will reach the needle suture and remove it from the suture towel and deliver it to the surgeon's hand. It can be seen that with this procedure much of the nurse's time and effort is required to handle the suture. This is an extremely inefficient arrangement when it is realized that the time and effort of a nurse in an operating room must be spent in the most expeditious and efficient manner possible.

According to U.S. Patent No. 3,363,751, a package was provided wherein handling of the suture was reduced to a minimum. As disclosed therein, a package was provided of flexible material folded to form separate compartments for the needle and the suture. By virtue of this arrangement, the preliminary step of removing the needle suture from the package and placing it on the suture towel is completely eliminated. Rather, where the nurse previously placed the uncoiled suture, she could place the suture package with the suture still contained therein. This result was obtained because the package was so designed that one

could pull the suture directly out of the package with practically the same ease and speed previously required to remove the suture from the suture towel. That is, the suture could be pulled directly out of the package in condition for immediate use without any unwinding or other manipulation of the suture. Moreover, the suture so removed from the suture package was absolutely free of tangles. Any previously known suture package which was not adapted for direct pulling of the suture could not be handled in the same manner since tangling would inevitably occur.

While the package disclosed in U.S. Patent No. 3,363,751 served eminently in the foregoing respects, it was observed that the needle was occasionally inadvertently dislodged from the package prior to the time when it was desired to do so. It is an object of the present invention to provide a package of the type described in which the suture needle is restrained from accidental dislodgement from the package.

The foregoing and other objects which will be apparent to those skilled in the art are achieved according to the invention by providing in a package of the type described a pocket formed in at least one layer of the folded packaging material forming walls of the compartment in which the suture needle

is located material for flat, elongated compartment material, disposed in a disposed in a the main portion of at least the compartment extending one of the package needle in the the package second compartment restrain the package.

Fig package according to manner of formation

Fig of formation of the package

Fig removal of a Figures 1-4;

located. The package comprises foldable packaging material folded at least twice to form a generally flat, elongate package having at least two separate compartments formed by the folded layers of packaging material, the main portion of the suture being disposed in a first compartment, the needle being disposed in a second compartment and out of contact with the main portion of the suture due to the presence of at least one layer of packaging material between the compartments, the remaining portion of the suture extending out of the first compartment, over an edge of the package, and being secured to the suture needle in the second compartment, at least one of the packaging surfaces defining the walls of said second compartment being provided with a pocket to restrain the needle from being dislodged from the package.

Figures 1-3 illustrate diagrammatically a package according to the invention and indicate the manner of forming same;

Figure 4 diagrammatically illustrates a method of forming a needle retaining pocket in the wall of the package of Figures 1-3;

Figure 5 diagrammatically illustrates the removal of a suture needle from the package of Figures 1-4;

Figure 6 shows an alternative form of pocket in the package wall;

Figures 7 and 8 show alternative arrangements for the disposition of the suture in the package; and

Figures 9 through 12 diagrammatically show alternative packages according to the invention.

With reference to figures 1-5, the main portion 1 of a suture 2 attached to a needle 3 is disposed in a back and forth, or zig-zag, manner on the central portion 4 constituting about one third of the area of a sheet of heavy paper 5. The package is then folded along line 6 to bring free portion 7 of the paper sheet 5 over the main portion 1 of the suture 2 to provide a first compartment defined by layers 4 and 7 of the folded packaging material. The needle 3 is located on the upper surface 9 of layer 7 and the remaining, minor, portion 10 of the suture extends out of the package, over edge 11 of the package end, and to the needle 3 located on surface 9 of layer 7. Layer 12 is then folded along line 13 over surface 9 of layer 7 to provide a second compartment defined by layers 7 and 12 and separated from the first compartment by layer 7 of the foldable packaging material located between the compartments. The surfaces defining the walls of the second compartment are then provided with a pocket by passing the rollers through opposed pressure rollers

as shown d
are spaced
against th
ing to the

in the defo
surfaces de
ment. The
rotation in
operated by

The
manner as s
needle 3 is
suture is t
pulling the
ities 14 an
12 have pro
dislodgemen
er 12.

The
package acc
able materi
foldable ma
together al
Where a sing
a laminated

as shown diagrammatically in Figure 4. The rollers are spaced sufficiently to exert a compressive force against the package and, as a result, a pocket conforming to the configuration of the needle is formed in the deformable paper packaging material in the surfaces defining the walls of the second compartment. The pressure-applying rollers are mounted for rotation in a conventional manner and may be manually operated by a crank (not shown).

The package is opened in the conventional manner as shown in Figure 5. After raising layer 12 needle 3 is easily tipped out of the package. The suture is then pulled from its compartment by simply pulling the needle outwardly of the package. The cavities 14 and 15 formed, respectively in layers 7 and 12 have proven effective to restrain the needle from dislodgement from the package prior to raising layer 12.

The package material useful in making a package according to the invention may be any foldable material and may comprise a single sheet of foldable material or a plurality of sheets joined together along fold lines by a foldable material. Where a single sheet is used, the sheet may comprise a laminated or coated sheet or a unitary sheet, for

example, of paper. In any event, the sheet is foldable to form a generally flat package. Where a plurality of sheets are used, the sheets need not be foldable provided that they are joined together along suitable fold lines by a material which is foldable. Suitable packaging material includes paper, cardboard, cloth, metal foil, plastic film and the like.

Irrespective of the type of packing material employed, at least one of the walls of the compartment making up the needle containing compartment is deformable under pressure to form a pocket or cavity for the needle. The pocket may be formed by making a depression in the wall (as shown in Figure 5) or by making one or more projections in the wall. Suitable projections can be made by passing a sheet of packaging material through embossing rolls which will provide one or more suitable raised projections. For example, a rectangular projection 16 shown in Figure 6 suitable for retaining a straight needle is readily provided by passing a sheet 5 of a paper or other deformable material through opposed embossing rolls. One of the rolls is provided with a rectangular projection which registers with a corresponding rectangular cavity in the other roll. It will be

clear tha
in the pa
than that
faces of
a plurali
ditioned t
the packa
vided with
le-retain
vided with
ions. Fur
with a nee
may be pre
registry
to retain
Th
does not r
it is prov
"pocket" o
in this se
hole throu
is provide
ed to prev
package wa
the needle

58,504/69

clear that projections suitable to retain the needle in the package can be provided in forms different than that shown. For, example, the appropriate surfaces of layer 7 and/or layer 13 can be provided with a plurality of unconnected ridges or projections positioned to restrain dislodgement of the needle from the package. Alternatively, one surface may be provided with one or more projections defining a needle-retaining cavity and the other surface can be provided with cavities which register with such projections. Further, where one of the surfaces is provided with a needle-retaining cavity, the opposite surface may be provided with a corresponding projection in registry with the cavity which cooperates therewith to retain the needle in the closed package.

The pocket provided according to the invention does not penetrate entirely through the layer in which it is provided. It is to be understood that the word "pocket" or the word "cavity" as used herein is limited in this sense and does not include an aperture or hole through the layer in which the cavity or pocket is provided. Such holes or apertures are to be avoided to prevent exposure of the needle through the outer package wall and to prevent possible entanglement of the needle in the main portion of the suture.

The suture is disposed in the package in a manner to be pulled from the package without snarling. This result is conveniently accomplished by laying out the suture in a back and forth, or zig-zag pattern such that the suture is essentially untwisted. Several suitable patterns are shown in Figures 1, 2, 7, and 8. In each of these patterns, the suture is laid flat in a back and forth manner by imparting a slight twisting motion each time the suture changes direction. However, each such twist is of opposite hand and the net effect is to impart essentially no net twist along the entire length of suture. Accordingly, when the needle is pulled linearly from the package, the main portion of the suture is dispensed linearly without snarling. The suture can be laid out with no overlap as shown in Figure 1 or with overlap as shown in Figures 7 and 8. In the event that successive turns of the suture overlap, it is preferred that each successive turn is laid out on top of a preceeding turn to avoid snarling upon removal of the suture from the package.

It is not necessary, of course, that the package take the form shown in Figures 1-6. For example, the package may be arranged as shown in Figures 9 and 10. In this embodiment, the package blank

is "L" shaped embodiment is formed by overlapping layers of material at the top of the compartment along the line of the cavity for the compartment does not form the side of the section 18 as shown in portion 19 containing line 22 of the compartment. After the section 12 or, the compartment can be formed by layer 19 and form the side. Several other embodiments are apparent and have additional features to provide additional

is "L" shape rather than rectangular as in the embodiment shown in Figure 1. The suture compartment is formed by folding layer 7' along line 6' over layer 4' and the needle 3 is then located on top of layer 7' as shown in Figure 10. The needle compartment is then formed by folding layer 12' along line 13' over layer 7', and the pocket or cavity formed in at least one wall of the needle compartment in the usual manner. Further, the suture does not require to be arranged in the central portion of the sheet but may be located at an external portion 18 as shown in Figure 11. In that event, central portion 19 is folded along line 20 to form the suture-containing compartment and layer 21 is folded along line 22 over layer 19 to form the suture needle compartment. The suture needle compartment can be formed after the suture compartment as shown in Figures 11 and 12 or, alternatively, the suture needle compartment can be formed first by folding layer 21 over layer 19 and then folding again along line 20 to form the suture compartment between layers 21 and 18. Several other arrangements suggest themselves and will be apparent. Additionally, of course, the package may have additional layers and these may be desired to provide additional security against dislodgement of

the suture and/or the suture needle. The preferred package, however, is a three layer package. Where the suture is retained in the package by opposed layers folded along lines such that the suture is restrained from lateral removal from the package by folded edges. In any event, the package will include the needle-retaining pocket described above and it will be understood that the cavity has been omitted from Figures 9-12 for simplicity.

As mentioned above, the pocket may be formed by passing the finished package, containing the suture and needle, through pressure rolls. Alternatively, the finished package can be subjected to static pressure in a conventional press. Further, of course the pocket can be provided in the sheet prior to making the package or in a blank form which the individual sheets are cut.

The package according to the invention is generally flat and includes at least three panels or layers of foldable packaging material. In the preferred embodiment, the package includes a top panel which can be raised to open the needle compartment which is defined by the top panel and an underlying panel. The needle compartment is provided with the needle-retaining pocket mentioned above. The main portion of the

suture is
and a bot
can be pr
needle co
panel def
ment cont
ed by two
arated fr
layer of
include a
the packag
out over t

necessary
one hand a
the needle
ed to the
ition that
from the p
first hand
pletely un
when neede
from the p
the needle
reper is

suture is provided between that underlying panel and a bottom panel. While other layers or panels can be provided, the package will always include a needle containing compartment openable by raising a panel defining a wall thereof and a separate compartment containing the main portion of the suture, defined by two layers of the packaging material, and separated from the needle compartment by at least one layer of packaging material. Both of the compartments include at least one opening end along one edge of the package and the suture extends between the needle out over this edge and into the suture compartment.

To remove the suture from the package it is necessary only to raise the panel over the needle with one hand and tilt the package slightly downward so that the needle falls free. The needle will thus be presented to the other hand of the operator in such a position that it may be readily grasped to pull the suture from the package while holding the package with the first hand. A straight uncoiled needle suture, completely untangled and untwisted, is thus presented, when needed, to be taken directly and immediately from the package. It should be also noted that when the needle falls downwardly, the neck behind the needle is presented to the hand of the operator so

that there is no need to unnecessarily contaminate the needle point. Also the chances of the operator inadvertently sticking himself with the tip of the needle are reduced.

An extra advantage provided by the present invention is that more efficient and more useful labeling of the suture is made possible. Previously the suture was removed completely from its package and laid out on the suture towel. Consequently, accurate identification of the suture at that point was severely hampered. On the other hand, since the present invention allows the suture to remain in its package until the moment it is delivered to the hand of the surgeon for use, it is manifest that the suture will be properly identified and labeled at all times, thereby avoiding confusion and possible use of the wrong type of suture.

The package shown is open. Such packages will generally be enclosed in a sterile condition before use inside a sealed outer envelope. The outer envelope can vary widely in configuration but should be sterilizable and should protect the sterile inner package from contamination. Suitable packaging materials include glass, plastic, metal, etc. and may be rigid or flexible. Resin coated paper or metal foil

or other
are parti-
erally pro

in a prede
such as a
package is

envelope u
Since both
identifying

By :
it is poss:

used in U.S
to minimize
of the suture

The
the underly
grasped :

or other readily heat sealable packaging materials are particularly suitable. The outer package is generally provided with means to open the outer package in a predetermined manner to expose the inner package such as a tear strip or other known arrangement. The package is conveniently removed, from the sealed envelope using sterile techniques prior to use.

Since both the package and the envelope may include identifying indicia, no possible confusion can arise.

By providing a package as disclosed herein, it is possible to obtain all of the advantages disclosed in U.S. Patent No. 3,363,751 and, in addition, to minimize likelihood of accidental dislodgement of the suture needle from the package.

The top panel may be made slightly wider than the underlying panels to form a flap which can easily be grasped for opening the package.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A package containing a suture having a needle attached thereto comprising foldable packaging material folded at least twice to form a generally flat, elongated package having at least two separate compartments formed by the folded layers of packaging material, the main portion of said suture being disposed in a first of said compartments the needle being disposed in a second of said compartments and out of contact with the main portion of said suture due to the presence of at least one layer of packaging material between said compartments, the remaining portion of said suture extending out of said first compartment, over an edge of the package, and being secured to the suture needle located in said compartment, at least one of the surfaces of the packaging material defining the walls of said second compartment being provided with a pocket to restrain said needle from being dislodged from the package. (25th April, 1969)

2. A package according to claim 1 wherein said pocket is formed by a depression in said surface of the packaging material, said needle being located within said pocket. (25th April, 1969)

3.

the size
correspon

4.

said pocket
said surface

5.

pocket is
said pocket
pocket.

6.

the main po
first compa
such that t
linearly fr

7. A

the package
packaging ma
compartment
material and
folded there

3. A package according to claim 2 wherein the size and shape of said pocket substantially corresponds to the size and shape of the needle.

(25th April, 1969)

4. A package according to claim 1 wherein said pocket is formed by at least one projection in said surface of the packaging material.

(25th April, 1969)

5. A package according to claim 4 wherein said pocket is formed by a single projection surrounding said pocket, said needle being located within said pocket.

(25th April, 1969)

6. A package according to claim 1 wherein the main portion of the suture is laid out in said first compartment in a back and forth configuration such that the suture is not twisted upon being pulled linearly from the package.

(25th April, 1969)

7. A package according to claim 1 wherein the package is formed by twice folding a flexible packaging material, the first fold forming said first compartment between a bottom layer of the packaging material and a first layer of packaging material folded thereover, and the second fold forming said

58,504/69

second compartment between said first layer and second layer of packaging material folded over said first layer. (25th April, 1969)

8. A package according to claim 7 wherein the main portion of the suture is laid out in said first compartment in a back and forth configuration such that the suture is not twisted upon being pulled linearly from the package.

(25th April, 1969)

9. A package according to claim 8 further including an outer wrapper sealing the package thereinside.

(25th April, 1969)

10. A method of forming a suture needle package comprising the steps of providing a package comprising foldable packaging material folded at least twice to form a generally flat, elongate package having at least two separate compartments formed by the folded layers of packaging material, the main portion of said suture being disposed in a first of said compartments, the needle being disposed in a second of said compartments and out of contact with the main portion of said suture due to the presence of at least one layer of packaging material between said compartments, the remaining portion of said suture extending out of said first compartment, over an edge of the package; and being

secured
compartm
said nee
deformat
said sec
to restr
package.

ially as
the accom
cribed.

DA

DE

By

CL

Fel



58,504/69

secured to the suture needle located in said second compartment, and subjecting the package containing said needle to externally applied pressure to cause deformation of at least one of the walls defining said second compartment to form a pocket therein to restrain said needle from dislodgement from the package. (25th April, 1969)

11. A package containing a suture substantially as hereinbefore described with reference to the accompanying drawings. (25th April, 1969)

12. A method substantially as herein described. (25th April, 1969)

DATED this 15th day of MAY, 1969.

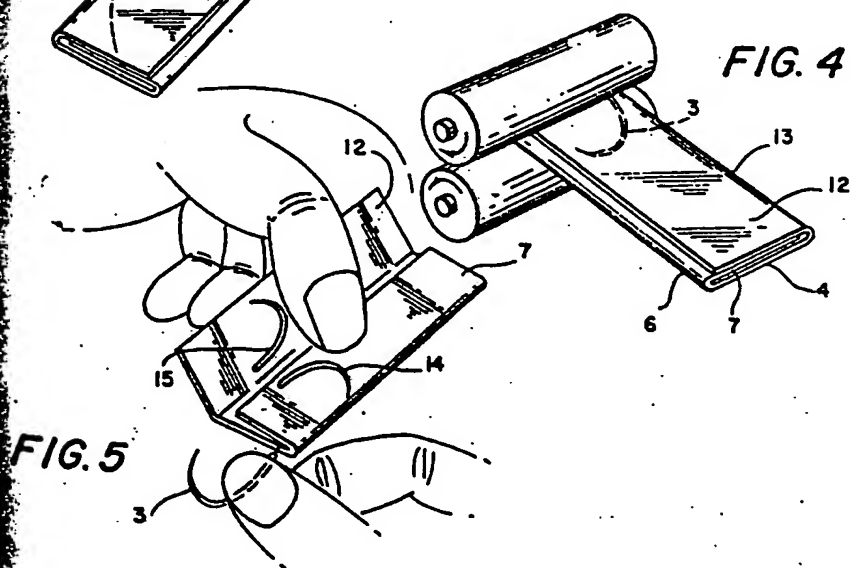
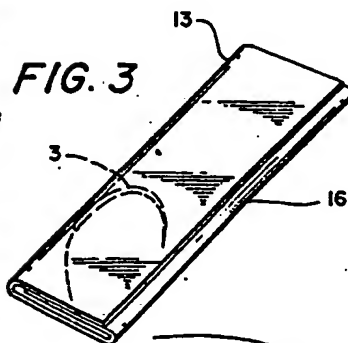
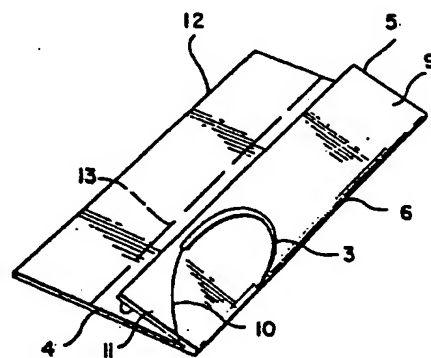
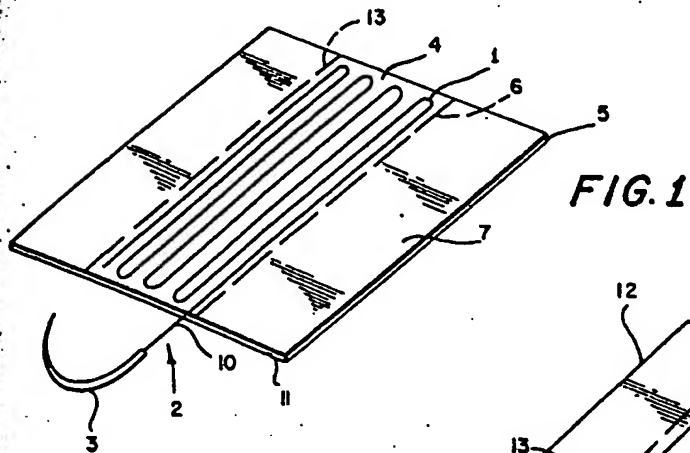
DEKNATEL INC.

By its Patent Attorneys

CLEMENT HACK & CO.

Fellows Institute of Patent
Attorneys of Australia.





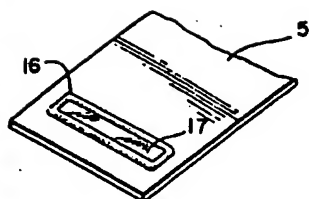


FIG. 6

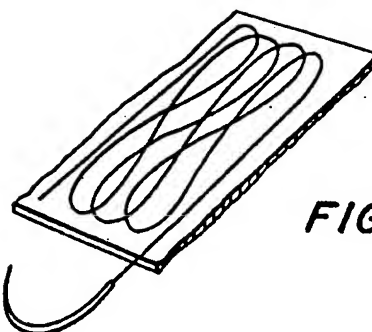


FIG. 7

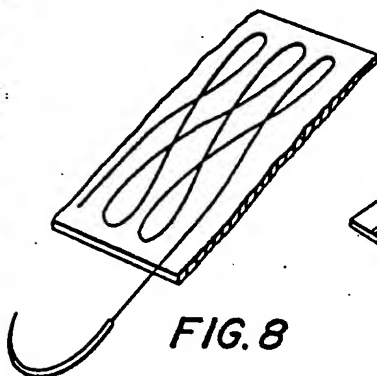


FIG. 8

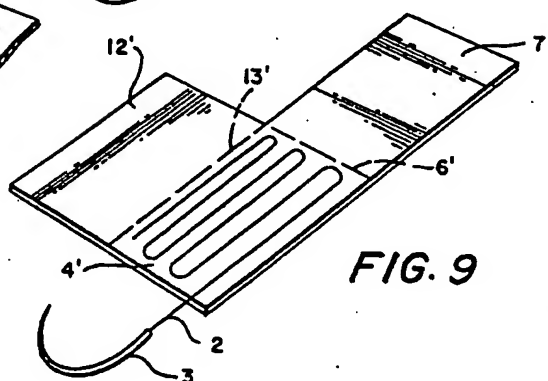


FIG. 9

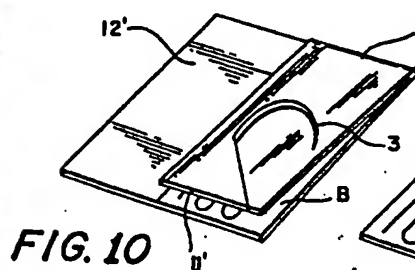


FIG. 10

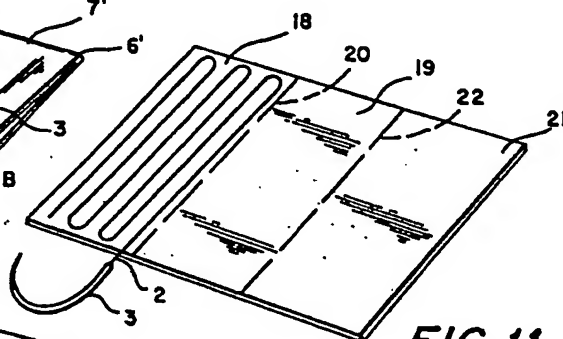


FIG. 11

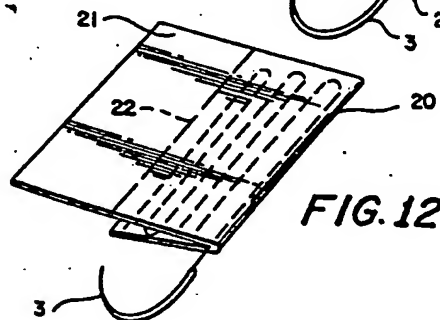


FIG. 12

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

☒ BLACK BORDERS

☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES

☒ FADED TEXT OR DRAWING

☒ BLURRED OR ILLEGIBLE TEXT OR DRAWING

☐ SKEWED/SLANTED IMAGES

☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS

☐ GRAY SCALE DOCUMENTS

☐ LINES OR MARKS ON ORIGINAL DOCUMENT

☒ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY

☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.